DRONCIT FELINE CESTOCIDE- praziquantel tablet Bayer HealthCare, LLC Animal Health Division

Droncit[®] (praziquantel)

Feline Cestocide Tablets

CAUTION: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

Each Tablet Contains 23 mg Praziquantel

DESCRIPTION:

Droncit[®] Feline Cestocide Tablets are sized for easy oral administration to either adult cats or kittens. The tablets may be crumbled and mixed with the feed.

INDICATIONS:

Droncit[®] Feline Cestocide Tablets are indicated for the removal of the following feline cestodes: *Dipylidium caninum* and *Taenia taeniaeformis*.

CONTRAINDICATIONS:

There are no known contraindications to the use of praziquantel in cats.

ACTION:

Droncit[®] (praziquantel) is absorbed, metabolized in the liver and excreted in the bile. Upon entering the digestive tract from the bile, cestocidal activity is exhibited.¹

Following exposure to praziquantel, the tapeworm loses its ability to resist digestion by the mammalian host. Because of this, whole tapeworms, including the scolex, are very rarely passed after administration of praziquantel. In many instances only disintegrated and partially digested pieces of tapeworms will be seen in the stool. The majority of tapeworms killed are digested and are not found in the feces.

USE DIRECTIONS:

Droncit[®] Feline Cestocide Tablets may be administered directly per os or crumbled and mixed with the feed. The recommended dosage of praziquantel varies according to body weight. Smaller animals require a relatively larger dosage because of their higher metabolic rate. The optimum dose for each individual animal will be achieved by utilizing the following dosage schedule:

Cats and Kittens*		
4 pounds and under	½ tablet	
5-11 pounds	1 tablet	
Over 11 pounds	1 ½ tablets	

^{*} Not intended for use in kittens less than 6 weeks of age.

FASTING:

The recommended dosage of praziquantel is not affected by the presence or absence of food in the gastrointestinal tract, therefore, **FASTING IS NEITHER NECESSARY NOR RECOMMENDED.**

RETREATMENT:

For those animals maintained on premises where reinfections are likely to occur, clients should be instructed in the steps necessary to prevent reinfection; otherwise, retreatment may be necessary. This is especially true in cases of *Dipylidium caninum* infections where reinfection is almost certain to occur if fleas are not removed from the animal and its environment.

ANIMAL SAFETY:

The safety index has been derived from controlled safety evaluations, clinical trials and prior approved use in foreign countries.

Dosages of 5 times the labeled rate at 14 day intervals to cats as young as 5 ½ weeks did not produce clinical signs of toxicity. No significant clinical chemistry, hematological, or histopathological changes occurred. Symptoms of gross overdosage include vomition, salivation, diarrhea and depression.

PREGNANCY:

Droncit[®] (praziquantel) has been tested in breeding and pregnant cats. No adverse effects were noted.

ADVERSE REACTIONS:

One instance of diarrhea and one of salivation (1.5%) were reported during the field trials in which 135 cats were administered Droncit[®] Feline Cestocide.

For medical emergencies or to report adverse reactions, call 1-800-422-9874.

WARNING:

Keep out of the reach of children. Not for human use.

For customer service or to obtain product information, including Material Safety Data Sheet, call 1-800-633-3796.

STORAGE:

Store at less than or equal to 25°C (77°F)

HOW SUPPLIED:

Bottle of 50 and 150 scored tablets. Each scored tablet contains 23 mg praziquantel.

Product Code 08713165-182999 — 50 Tablets

Product Code 08713211-185599 — 150 Tablets

REFERENCES:

¹ Andrews, P. Pharmacokinetic Studies with Droncit in Animals Using a Biological Assay. *Veterinary Medical Review* 2/76: 154-165.

Bayer HealthCare LLC, Animal Health Division Shawnee Mission, Kansas 66201 U.S.A. NADA 111-798, Approved by FDA Made in Germany

Bayer, the Bayer Cross, and Droncit are registered trademarks of Bayer.

08954391, R.2 ©2014 Bayer HealthCare LLC April, 2014 19062

Principal Display Panel – 50 Tablets



with the feed. FASTING IS NEITHER NECESSARY NOF Tablets may be given directly or crumbled and offered

For removal of Dipylidium caninum and Taenia taeniaeformis

Feline Cestocide Tablets

EACH TABLET CONTAINS: 23 mg praziquantel. CAUTION: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

WARNING: KEEP OUT OF REACH OF CHILDREN.

Bayer

50 Tablets

Bayer HealthCare LLC, Animal Health Division Shawnee Mission, Kansas 66201, USA NADA 111-798, Approved by FDA Made in Germany

DOSAGE AND ADMINISTRATION: Administer orally to cats as follows:

No. of Tablets

Body Weight (lbs.)

1.0 4 and under 5-11 over 11

SOLD TO VETERINARIANS ONLY

© 2014 Bayer HealthCare LLC. Bayer, the Ba Cross and Droncit are registered trademarks of Bayer.

08713165-182999

Feline Cestocide Tablets

 $\textbf{Droncit}^{\mathbb{R}}$

23

(praziquantel)

EACH TABLET CONTAINS: 23 mg praziquantel.

CAUTION: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

WARNING: KEEP OUT OF REACH OF CHILDREN.

BAYER 50 Tablets

Bayer HealthCare LLC, Animal Health Division Shawnee Mission, Kansas 66201, USA NADA 111-798, Approved by FDA Made in Germany

Principal Display Panel – 150 Tablets

Tablets may be given directly or crumbled and offered with the feed. FASTING IS NEITHER NECESSARY For removal of Dipylidium caninum and Taenia taeniaeformis See package insert for complete details. TORAGE: Store at less than or equal to 25°C (77°F)



EACH TABLET CONTAINS: 23 mg praziquantel. **CAUTION:** Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian. WARNING: KEEP OUT OF REACH OF CHILDREN.

Bayer

150 Tablets

Bayer HealthCare LLC, Animal Health Division Shawnee Mission, Kansas 66201, USA NADA 111-798, Approved by FDA Made in Germany

DOSAGE AND ADMINISTRATION: Administer orally to No. of Tablets Body Weight (lbs.) cats as follows:

1.5 4 and under 5-11 over 11

SOLD TO VETERINARIANS ONLY

2014 Bayer HealthCare LLC. Bayer, the Bayer Cross and Droncit are registered trademarks of Bayer.

08954502, R.2

9064

08713211-185599

Droncit® (praziquantel) 23

Feline Cestocide Tablets

EACH TABLET CONTAINS: 23 mg praziquantel.

CAUTION: Federal (U.S.A.) law restricts this drug to use

by or on the order of a licensed veterinarian.

WARNING: KEEP OUT OF REACH OF CHILDREN.

150 Tablets

BAYER

Bayer HealthCare LLC, Animal Health Division Shawnee Mission, Kansas 66201, USA NADA 111-798, Approved by FDA Made in Germany

DRONCIT FELINE CESTOCIDE

praziquantel tablet

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0859-2128
Route of Administration	ORAL	DEA Sche dule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PRAZIQUANTEL (UNII: 6490C9U457) (PRAZIQUANTEL - UNII:6490C9U457)	PRAZIQUANTEL	23 mg	

Product	Characteristics	

Color WHITE (White to off white) Score 2 pieces

Shape	ROUND	Size	10 mm
Flavor		Imprint Code	Droncit;23
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0859-2128-01	50 in 1 BOTTLE		
2	NDC:0859-2128-02	150 in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA111798	12/11/1981		

Labeler - Bayer HealthCare, LLC Animal Health Division (152266193)

Revised: 2/2015 Bayer HealthCare, LLC Animal Health Division